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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,325	04/24/2001	Mark Modell	MDS-009CN (6219/15)	6590
21323	7590	02/18/2004	EXAMINER	
TESTA, HURWITZ & THIBEAULT, LLP HIGH STREET TOWER 125 HIGH STREET BOSTON, MA 02110			SMITH, RUTH S	
			ART UNIT	PAPER NUMBER
			3737	14
DATE MAILED: 02/18/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/841,325

Applicant(s)

MODELL ET AL.

Examiner

Ruth S Smith

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 105-111 and 113-147 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 105-111 and 113-147 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10.11.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 105-109, 111, 115-120, 122, 123, 126-131, 133, 134, 137-141, 143, 144, 147 are rejected under 35 U.S.C. 102(b) as being anticipated by Kittrell et al. Kittrell et al disclose a method of analyzing tissue to determine its state by illuminating the tissue using an optical assembly comprising a moveable mirror (125, 98, 48) to focus electromagnetic radiation on sequential regions of the tissue. The catheter and optical fibers provide the sheath for transmitting the radiation. Radiation emanating from the sequential regions is detected and analyzed to determine the characteristic of the tissue. The detected radiation is compared to a standard in order to determine the health of the tissue. The light that is detected can be detected with the same fiber which transmits the light to the tissue. Therefore, the emanating EM radiation is substantially confocal with the illuminating EM radiation. With respect to claim 107, the collected radiation is sent to a detector using a mirror 68 that is moveable with respect to the patient. With regard to claim 115, any structural element is capable of being disposed of after a single use. The radiation emanating from the tissue is detected with a detector array. The structure set forth in claims 118-119 are seen in figure 23., elements 68, 70. With regard to claims 120, 122, 123, the field stops are provided by the optical fiber entrances and the mirror controls the field stops in order to probe a specific volume element of the tissue.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3737

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 110,113,114,121,124,125,132,135,136,142,145,146 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al. Kittrell et al disclose a method of analyzing tissue to determine its state by illuminating the tissue using an optical assembly comprising a moveable mirror (125, 98,48) to focus electromagnetic radiation on sequential regions of the tissue. The catheter and optical fibers provide the sheath for transmitting the radiation. Radiation emanating from the sequential regions is detected and analyzed to determine the characteristic of the tissue. The detected radiation is compared to a standard in order to determine the health of the tissue. The radiation emanating from the tissue is detected with a detector array. The light that is detected can be detected with the same fiber which transmits the light to the tissue. Therefore, the emanating EM radiation is substantially confocal with the illuminating EM radiation. With respect to claim 110, it would have been obvious to one skilled in the art that the teachings of Kittrell et al would be applicable to any tissue type. With respect to claim 113, the wavelengths selected would have been obvious to one skilled in the art based on the type of tissue analyzed and the type of procedure being performed. With respect to claim 114, one skilled in the art would have known to analyze the entire sample in order to be sure of an accurate analysis of the tissue. With regard to claim 124, in the absence of any showing of criticality, the specific number of mirrors used to illuminate the tissue would have been an obvious design choice. With respect to claim

121, in that the claim fails to positively set forth the field stop is used in a manipulative sense, in the absence of any showing of criticality, the specific field stop dimension used would have been an obvious design choice of known equivalents in the art.

### ***Response to Arguments***

Applicant's arguments filed 12/5/03 have been fully considered but they are not persuasive. The light that is detected can be detected with the same fiber than transmits the light to the tissue. Therefore, the emanating EM radiation is substantially confocal with the illuminating EM radiation. With respect to the use of field stops, the field stops are provided by the optical fiber entrances and the mirror controls the field stops in order to probe a specific volume element of the tissue.

### ***Conclusion***

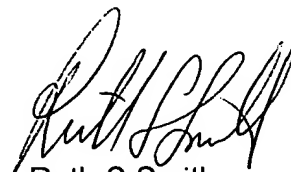
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Ruth S. Smith', is positioned above the printed name.

Ruth S Smith  
Primary Examiner  
Art Unit 3737

RSS